

## Floxin<sup>®</sup> Otic (ofloxacin otic) Solution 0.3%

FLOXIN<sup>®</sup> Otic (ofloxacin otic solution) 0.3% contains 3 mg/mL ofloxacin with 0.0025% benzalkonium chloride, 0.9% sodium chloride, and water for injection. Hydrochloric acid and sodium hydroxide are added to adjust the pH to 6.5 ± 0.5.

FLOXIN Otic is an ototopical fluoroquinolone that exerts its antibacterial activity by inhibiting DNA gyrase and its action is bactericidal.

FLOXIN Otic is available in 5 mL and 10 mL plastic dropper bottles and as single dispensing containers. Each single dispensing container delivers 0.25 mL of FLOXIN Otic, which is equivalent to 5 drops from the 5 mL or 10 mL bottles.

### FLOXIN Otic Indications and Dosing:

Otic Infection	Pathogens	Patient age	Dosage of FLOXIN Otic	Therapy Length
Otitis externa	<i>Staphylococcus aureus</i> <i>Pseudomonas aeruginosa</i> <i>Escherichia coli</i>	6 months to 13 years	5 drops (0.25 mL) instilled into the affected ear once daily	7 days
		≥ 13 years	10 drops (0.5 mL) instilled into the affected ear once daily	7 days
Acute otitis media with tympanostomy tubes	<i>Staphylococcus aureus</i> <i>Streptococcus pneumoniae</i> <i>Haemophilus influenzae</i> <i>Moraxella catarrhalis</i> <i>Pseudomonas aeruginosa</i>	1 to 12 years	5 drops (0.25 mL) instilled into the affected ear twice daily	10 days
Chronic suppurative otitis media with perforated tympanic membranes	<i>Staphylococcus aureus</i> <i>Proteus mirabilis</i> <i>Pseudomonas aeruginosa</i>	≥ 12 years	10 drops (0.5 mL) instilled into the affected ear twice daily	14 days

- FLOXIN Otic was the first ototopical antibiotic approved for use in the middle ear and remains the only ototopical antibiotic with three otitis indications: otitis externa (OE), acute otitis media with tympanostomy tubes (AOMTT) and chronic suppurative otitis media (CSOM) with perforated tympanic membranes.
- FLOXIN Otic has comparable clinical cure rates to Augmentin<sup>®</sup> (amoxicillin/clavulanate) oral suspension therapy for treatment of AOMTT.<sup>2</sup>

### FLOXIN Otic Important Safety Information:

- FLOXIN<sup>®</sup> Otic is contraindicated in patients with a history of hypersensitivity to ofloxacin, other quinolones, or other ingredients of the medication. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving systemic quinolones. At the first sign of allergic reaction, stop taking the drug. Patients who have not improved after 1 week of treatment should be evaluated by their healthcare provider.
- The most common reported adverse reactions in clinical trials in AOM patients with TT and CSOM patients treated twice daily with FLOXIN<sup>®</sup> Otic (n=656) were taste perversion (7%), earache (1%), pruritus (1%), paraesthesia (1%), rash (1%), and dizziness (1%).
- The most common reported adverse reactions in 3 clinical trials (n=799) in OE patients treated once daily with FLOXIN<sup>®</sup> Otic were application site reaction (0.6%-16.8%), pruritus (1%-1.2%), earache (0.6%-0.8%), dizziness (0.0%-0.6%), and headache (0.2%-0.3%). In 2 of these clinical studies (n=310), the higher application site reaction rate resulted from the specific questioning of subjects.
- Please also see Full Prescribing Information [[http://www.floxinotic.com/prescribing\\_info.htm](http://www.floxinotic.com/prescribing_info.htm)].

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#### References:

- FLOXIN<sup>®</sup> Otic (ofloxacin otic solution) 0.3% prescribing information
- Goldblatt EL, Dohar J, Nozza J, et al. Topical ofloxacin versus systemic amoxicillin/clavulanate in purulent otorrhea in children with tympanostomy tubes. International Journal of Pediatric Otorhinolaryngology 1998; 46: 91-101